

Application Ser. No.: 10/031,764
Filing Date: September 30, 2002
Examiner: Audet, Maury A.

Remarks

In the Office Action, making the action final, the Examiner has noted that claims 1-7, 9 and 10 are pending in the application; claims 1-3, 6, 7, 9 and 10 are rejected; and that claims 4 and 5 are objected to. By this amendment, claims 1, 6 and 10 have been amended. Thus, claims 1-7, 9 and 10 are pending in the application. No new subject matter has been inserted through these amendments. All of the amendments are fully supported by the specification. Specifically, claim 1 was amended to provide a proviso that both R_8 and R_9 are not simultaneously hydrogen. Support for this can be found in the specification at page 3, line 27 where it is stated that "Ideally in the first embodiment R_8 and/or R_9 is $-CH_2$ -secondary amine," which necessitates that at least one of R_8 and/or R_9 is not hydrogen. As a result, claim 6 has been amended to delete the phrase "and R_8 and R_9 are both H." Claim 10 is amended to affirmatively recite in step (c) reaction of product from step (b) with a secondary amine to form compound of claim 1, support for which can be found at various places in the specification and more particularly at page 10, lines 18 to 23. The Examiner's rejections are respectfully traversed below.

Rejection Under 35 U.S.C. § 102(b)

The Examiner has maintained rejection of claims 1-3, 6-7, and 9-10 under 35 U.S.C. 102(b) as being anticipated by either Balkovec et al. I (US 5,378,804; also cited within Applicant's PCT/EP00/06769 Form 409 as Document 4 (D4), under it's WO continuity WO-A-9421677) or Balkovec et al. II (US 5,541,160; also cited within Applicant's PCT/EP00/06769 Form 409 as Document 1 (D1), under it's WO continuity WO-A-9527074).

Specifically, the Examiner states that Applicant's arguments in their response of August 1, 2005 is not persuasive because "The core peptide is known, and as to these claims, the references still teach each and every limitation (more specifically, some or all of the various R groups, in some instances due to Applicant's alternative claims language; for instance, R_8 and R_9 are still taught since "H" alone may still be so attached (rather

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than just the alternative secondary amine structure, which Applicant's argument focused primarily on))."

Applicants respectfully submit that the Examiner's analysis is incorrect and further submit that claims 1-3, 6-7, and 9-10 are not anticipated by either Balkovec I or Balkovec II for the arguments and reasons of record. More particularly, Applicants draw Examiner's attention to the substituent R_1 of compound of formula (I) as recited in claim 1. The substituent R_1 is same as $-NR^{II}R^{III}$ of Balkovec I and R^3 of Balkovec II. The substituent R^3 of Balkovec II is defined as follows:

" R^3 represents [*which is same as R_1 of the present invention*] H, -OH, $-O(CH_2)_nNR^VR^{VI}$, where R^V and R^{VI} independently represent H or C_{1-4} alkyl, or $-O(CH_2)_nNR^VR^{VI}R^{VII}Y$, where R^V and R^{VI} are as defined above, R^{VII} represents H or C_{1-4} alkyl, n is an integer of from 2-6 inclusive, and Y represents a counterion."

On the other hand, please note that R_1 of the present invention is defined as follows:

" R_1 is selected from the group consisting of -CN; $-CH_2NH_2$; $-N_3$; aryl; substituted aryl; imidazolyl; morpholinoethylamino; -OR, wherein R is C_1 - C_{12} alkyl, substituted alkyl of $(CH_2)_n-X$, where n is 1-5 and X is selected from the group consisting of OH, aryl, Cl, Br, I, COOY and CN, wherein Y is selected from the group consisting of C_1 - C_6 alkyl, C_7 - C_{12} alkenyl, aryl, fused aryl, substituted aryl, a heterocyclic containing 1-3 heteroatoms, mono or di-substituted aminoalkyl and a hydroxy protecting group;"

It is apparent from the above that there is no overlap from R_1 of claim 1 with either Balkovec I or Balkovec II. That is, R_1 of claim 1 does not include $-NR^{II}R^{III}$ of Balkovec I or H, -OH, $-O(CH_2)_nNR^VR^{VI}$ or $-O(CH_2)_nNR^VR^{VI}R^{VII}Y$ of Balkovec II. Again, as we argued before, please note anticipation requires that each and every limitation must be present in a single prior art reference. As clearly stated by a court:

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Anticipation is established if *every element of a properly construed claim* is present in a single prior art reference¹ (emphasis added).

In fact, as we have clearly shown above compound of claim 1 does not claim any compounds of either Balkovec I or Balkovec II. Thus it is submitted that claim 1, as amended, does not anticipate either Balkovec I or Balkovec II.

Similarly, dependent claims 2-3, 6-7, and 9-10 depend directly or indirectly upon claim 1 and include all of the limitations of claim 1 and further recite additional limitations. Consequently, all of claims 1-3, 6-7 and 9-10 do not anticipate either Balkovec I or II, and therefore fully satisfy the requirements of 35 U.S.C. 102(b).

Nevertheless, in order to expedite the prosecution of this case, claim 1 has been further amended to recite affirmatively both R₈ and R₉ are not simultaneously hydrogen as commented by the Examiner. In view of the foregoing and for all of the reasons advanced above it is respectfully submitted that claims 1-3, 6-7, and 9-10 are not anticipated by either Balkovec I or Balkovec II and therefore withdrawal of rejection as to claims 1-3, 6-7 and 9-10 is respectfully requested.

Rejection Under 35 U.S.C. § 103(a)

The Examiner has also maintained rejection of claims 1-3, 6-7, and 9-10 under 35 U.S.C. 103(a) as being unpatentable over either Balkovec et al. I (US 5,378,804; also cited within Applicant's PCT/EP00/06769 Form 409 as Document 4 (D4), under it's WO continuity WO-A-9421677) or Balkovec et al. II (US 5,541,160; also cited within Applicant's PCT/EP00/06769 Form 409 as Document 1 (D1), under it's WO continuity WO-A-9527074).

In particular, the Examiner notes that Applicant's arguments in their response of August 1, 2005 have been considered and are not persuasive. However, as noted above, Applicants respectfully submit that claims 1-3, 6-7 and 9-10 recite novel compounds which are patentably distinguishable from either Balkovec I or Balkovec II for various

¹ See *Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.* 45 F.3d 1550, 1554 (33 USPQ2d 1496) (Fed. Cir. 1995).

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arguments presented in Applicants' response of August 1, 2005 and further enumerated above in response to rejections under 35 U.S.C. 102(b).

In addition, as also noted above, claim 1 has been further amended to affirmatively recite both R₈ and R₉ are not simultaneously hydrogen. More importantly, the Examiner has clearly indicated that "positions R₈ and R₉ are not reasonably taught or suggested by the prior art of record to contain the secondary amine structure..." while objecting to claims 4 and 5. Thus it is submitted that claim 1 as amended is also not taught by the prior art of record. Accordingly, it is respectfully submitted that claims 1-3, 6-7 and 9-10 as amended fully satisfy the requirements of 35 U.S.C. 103(a). Thus, withdrawal of rejection as to claims 1-3, 6-7, and 9-10 is respectfully requested.

Objection and Indication of Allowable Subject Matter

The Examiner has noted that claims 4 and 5 if amended to include all the limitations of the base claim from which they depend would likely receive favorable consideration.

In particular, Applicants note with much appreciation that the Examiner has remarked as to positions R₈ and R₉ which are not reasonably taught or suggested by the prior art of record to contain the secondary amine structure of claims 4-5. However, as noted above, claim 1 has been amended to include the limitation of at least one of R₈ and R₉ to be -CH₂-Sec.amine. Thus, it is submitted that claim 1, as amended, is also not taught or suggested by the prior art of record as admitted by the Examiner. Accordingly, it is respectfully submitted that claim 1 is in condition for allowance and thus obviating objection as to claims 4 and 5. Accordingly, withdrawal of objection as to claims 4 and 5 is respectfully requested.

Conclusions

In view of the above Remarks, it is respectfully submitted that claims 1-7 and 9-10 are now in condition for allowance and the early issuance of this case is respectfully

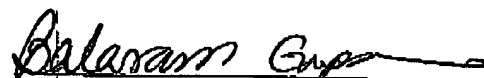
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requested. In the event the Examiner wishes to contact the undersigned regarding any matter, please call (collect if necessary) the telephone number listed below.

As noted above, Applicants are concurrently filing a request for continued examination with this submission.. Applicants request the Commissioner to charge these fees and any other fees that are deemed necessary due to this submission to Deposit Account No. 18-1982 for Aventis Pharmaceuticals Inc. Bridgewater, NJ. Please credit any overpayment to Deposit Account No. 18-1982.

Respectfully submitted,

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Encl: Transmittal for Request for Continued Examination (RCE) (1 page)

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